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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,830	03/08/2004	James E. Grimm	ZIM0417	2799

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EXAMINER

GEORGE, TARA R

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/795,830	Applicant(s) GRIMM ET AL.	
	Examiner TARA R. GEORGE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,8-19,21,23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4,8-10,15-19,21,23 and 25 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 2-4, 16-19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett et al. (5904691), in view of Hunter et al. (6235038).

With respect to claim 15, Barnett discloses a surgical system for use during an orthopedic surgical procedure at a surgical site of a patient's body, the system comprising: a surgical navigation system including means (e.g. computer) for tracking the position of an object during a surgical procedure; a navigated orthopedic guide (2) including means (e.g. biopsy guide) for being tracked by the surgical navigation system to guide positioning of the orthopedic guide (200 + 100 +106) at a desired position relative to the surgical site; means (4a-4d) for establishing a datum at a desired position relative to the surgical site; and a surgical component including means for engaging the datum positioned by the orthopedic guide to locate the surgical component at a desired position relative to the surgical site (102a-102d) (note col. 5 line 41 – col. 6 line 22).

Barnett does not appear to teach that the means for being tracked includes means that establishes datum.

Hunter teaches a system wherein an electromagnetic coil (at 90) is attached to the orthopedic guide (60) (also claim 17) and wherein sensors (70) are also placed at a base of said guide, in order to provide system that uses multiple navigational tools to provide better accuracy and flexibility for the user (col. 7 lines 60-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the orthopedic guide of Barnett with a tip that produces a signal that is trackable by a surgical navigational system in view of Hunter in order to provide system that uses multiple navigational tools to provide better accuracy and flexibility for the user.

As for claim 2, Barnett further discloses the surgical system of claim 15 wherein the means for establishing a datum comprises means for establishing one or more datums relative to the surgical site selected from the list consisting of pins, screws, bars, fins, rails, dovetails, planar surfaces, holes, slots, and/or notches (see fig. 1).

As for claim 3, Barnett further discloses the surgical system of claim 15 wherein the means for establishing a datum comprises means for establishing an intermediate datum separate from the guide itself (note use of 102a-102d).

As for claim 4, Barnett further discloses the surgical system of claim 15 wherein the means for establishing a datum comprises a guide body including a plurality of holes through the body for guiding the placement of pins relative to the surgical site (see fig. 1).

As for claim 8, Barnett further discloses the surgical system of claim 15 wherein the means for establishing a datum includes a base member (100) and a datum guide

member (200) connected to the base member such that the position of the datum guide member is adjustable relative to the base member to a desired datum guide member position as indicated by the surgical navigation system.

As for claim 16, Barnett further discloses the system of claim 15 wherein the means for tracking comprises multiple sensors (4a-4d) to detect and triangulate the position of the orthopaedic guide.

As for claim 18, Barnett further discloses the system of claim 15 wherein the means for establishing a datum comprises a drill guide to guide a drill in forming a hole in a bone at the surgical site (see col. 5 lines 37-40).

As for claim 19, Barnett further discloses the system of claim 15 wherein the means for establishing a datum comprises at least one hole (106) in the orthopaedic guide to guide placement of a pin adjacent the surgical site.

As for claim 21, Barnett further discloses the system of claim 15 wherein the surgical component comprises a cut guide to guide a cutter to cut a bone to receive an implant (see col. 5 lines 37-40).

As for claim 25, Barnett further teaches the system of claim 15 wherein the means for engaging the datum comprises at least one hole (106) formed in the surgical component to receive the datum in the form of a pin.

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Barnett which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the

law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 9, 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett and Hunter, as applied to claim 15, in view of Bowman et al. (4952213).

As for claims 9, 10 and 23, Barnett and Hunter do not disclose wherein the base member is able to be secured to a distal portion of a femur and the datum guide member is adjustable relative to the base member to establish a datum having desired flexion-extension and varus-valgus angles as indicated by the surgical navigation system; wherein the base member is able to be secured to a proximal portion of a tibia and the datum guide member is adjustable relative to the base member to establish a datum having desired posterior slope and varus-valgus angles as indicated by the surgical navigation system; and wherein the cut guide comprises a distal femoral cut guide.

Bowman teaches wherein a base member (24) is able to be secured to a distal portion of a femur and a guide member (10) is adjustable relative to the base member to establish desired flexion-extension and varus-valgus angles (see fig. 1); wherein the base member is able to be secured to a proximal portion of a tibia (see fig. 1) and the

guide member is adjustable relative to the base member to establish a desired posterior slope and varus-valgus angles (see fig. 1); and wherein the cut guide comprises a distal femoral cut guide (see fig. 1) in order to provide an apparatus for accurately positioning a cutting tool.

It is noted that the features taught by Bowman are very well known in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the base member and guide member of Barnett and Hunter in view of Bowman in order to provide the guide the ability to more accurately position a cutting tool.

Allowable Subject Matter

Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 11/9/09 have been fully considered but they are not persuasive. Barnett teaches the claimed invention except for the means for establishing a datum is includes a part of the orthopedic guide. Hunter is relied upon a teaching for why one would be motivated to incorporate such a means as part of the guide, as stated above. The Applicant is not claiming a new device or new technique. The MPEP establishes that obviousness is supported by combining prior art elements according to known methods to yield predictable results and that obviousness is supported by

applying a known technique to a known device ready for improvement to yield predictable results and some teaching and suggestion in the prior art that would have led one of ordinary skill to modify the prior art reference to arrive at the claimed invention (MPEP 2143 (A)(D)(G)).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARA R. GEORGE whose telephone number is (571)272-3402. The examiner can normally be reached on M-F from 6am-2pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. R. G./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733